

AMENDED IN ASSEMBLY JULY 3, 2013

AMENDED IN ASSEMBLY JUNE 24, 2013

AMENDED IN SENATE MAY 28, 2013

SENATE BILL

No. 294

Introduced by Senator Emmerson

February 15, 2013

An act to amend the heading of Article 7.5 (commencing with Section 4127) of Chapter 9 of Division 2 of, and to amend, repeal, and add Sections 4127, 4127.1, 4127.2, and 4400 of, the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

SB 294, as amended, Emmerson. Sterile drug products.

(1) The Pharmacy Law provides for the licensure and regulation of pharmacists and pharmacy corporations in this state by the California State Board of Pharmacy. Existing law requires the board to adopt regulations establishing standards for compounding injectable sterile drug products in a pharmacy. Existing law requires pharmacies to obtain a license from the board, subject to annual renewal, in order to compound injectable sterile drug products. A similar licensing requirement applies to nonresident pharmacies compounding injectable sterile drug products for shipment into California. A violation of the Pharmacy Law is a crime.

This bill, commencing July 1, 2014, would expand these provisions to prohibit a pharmacy from compounding or dispensing, and a nonresident pharmacy from compounding for shipment into this state, sterile drug products for injection, administration into the eye, or inhalation, unless the pharmacy has obtained a sterile compounding

pharmacy license from the board. The bill, commencing July 1, 2014, would specify requirements for the board for the issuance or renewal of a license, and requirements for the pharmacy as a licensee. The bill would require the board to adopt regulations to implement these provisions, as specified. By adding additional requirements to the Pharmacy Law concerning sterile drug products, the violation of which is a crime, the bill would impose a state-mandated local program.

(2) Existing law specifies the fee for issuance or renewal of a nongovernmental license to compound sterile drug products.

This bill, commencing July 1, 2014, would establish the fee for the issuance or renewal of a nonresident sterile compounding pharmacy license in the amount of \$780 and would require the applicant to deposit a reasonable amount, as determined by the board, necessary to cover the board's estimated cost of performing an inspection of the nonresident pharmacy location, as specified.

(3) The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes.
State-mandated local program: yes.

The people of the State of California do enact as follows:

1 SECTION 1. The heading of Article 7.5 (commencing with
2 Section 4127) of Chapter 9 of Division 2 of the Business and
3 Professions Code is amended to read:

4
5 Article 7.5. Sterile Drug Products

6
7 SEC. 2. Section 4127 of the Business and Professions Code is
8 amended to read:

9 4127. (a) The board shall adopt regulations establishing
10 standards for compounding injectable sterile drug products in a
11 pharmacy.

12 (b) The board shall adopt emergency regulations in accordance
13 with the Administrative Procedure Act (Chapter 3.5 (commencing
14 with Section 11340) of Part 1 of Division 3 of Title 2 of the
15 Government Code) to establish policies, guidelines, and procedures

1 to initially implement the provisions of this article that become
2 operative on July 1, 2014, including, but not limited to, building
3 standards adopted pursuant to Part 2.5 (commencing with Section
4 18901) of Division 13 of the Health and Safety Code. The initial
5 adoption, amendment, or repeal of a regulation authorized by this
6 section is deemed to address an emergency for purposes of Sections
7 11346.1 and 11346.6 of the Government Code, and the board is
8 hereby exempted for that purpose from the requirements of
9 subdivision (b) of Section 11346.1 of the Government Code. After
10 the initial adoption, amendment, or repeal of an emergency
11 regulation pursuant to this section, the board ~~shall not~~ *may* request
12 approval from the Office of Administrative Law to readopt the
13 regulation as an emergency regulation pursuant to Section 11346.1
14 of the Government Code.

15 (c) This section shall become inoperative on July 1, 2014, and,
16 as of January 1, 2015, is repealed, unless a later enacted statute,
17 that becomes operative on or before January 1, 2015, deletes or
18 extends the dates on which it becomes inoperative and is repealed.

19 SEC. 3. Section 4127 is added to the Business and Professions
20 Code, to read:

21 4127. (a) A pharmacy that compounds sterile drug products
22 for injection, administration into the eye, or inhalation shall possess
23 a sterile compounding pharmacy license as provided in this article.

24 (b) The board shall adopt regulations in accordance with the
25 Administrative Procedure Act (Chapter 3.5 (commencing with
26 Section 11340) of Part 1 of Division 3 of Title 2 of the Government
27 Code) to establish policies, guidelines, and procedures to
28 implement this article, including, but not limited to, building
29 standards adopted pursuant to Part 2.5 (commencing with Section
30 18901) of Division 13 of the Health and Safety Code.

31 (c) This section shall become operative on July 1, 2014.

32 SEC. 4. Section 4127.1 of the Business and Professions Code
33 is amended to read:

34 4127.1. (a) A pharmacy shall not compound injectable sterile
35 drug products in this state unless the pharmacy has obtained a
36 license from the board pursuant to this section. The license shall
37 be renewed annually and is not transferable.

38 (b) A license to compound injectable sterile drug products may
39 only be issued for a location that is licensed as a pharmacy.
40 Furthermore, the license to compound injectable sterile drug

1 products may only be issued to the owner of the pharmacy license
2 at that location. A license to compound injectable sterile drug
3 products may not be issued until the location is inspected by the
4 board and found in compliance with this article and regulations
5 adopted by the board.

6 (c) A license to compound injectable sterile drug products may
7 not be renewed until the location has been inspected by the board
8 and found to be in compliance with this article and regulations
9 adopted by the board.

10 (d) Pharmacies operated by entities that are licensed by either
11 the board or the State Department of Public Health and that have
12 current accreditation from the Joint Commission on Accreditation
13 of Healthcare Organizations, or other private accreditation agencies
14 approved by the board, are exempt from the requirement to obtain
15 a license pursuant to this section.

16 (e) The reconstitution of a sterile powder shall not require a
17 license pursuant to this section if both of the following are met:

18 (1) The sterile powder was obtained from a manufacturer.

19 (2) The drug is reconstituted for administration to patients by
20 a health care professional licensed to administer drugs by injection
21 pursuant to this division.

22 (f) This section shall become inoperative on July 1, 2014, and,
23 as of January 1, 2015, is repealed, unless a later enacted statute,
24 that becomes operative on or before January 1, 2015, deletes or
25 extends the dates on which it becomes inoperative and is repealed.

26 SEC. 5. Section 4127.1 is added to the Business and Professions
27 Code, to read:

28 4127.1. (a) A pharmacy shall not compound sterile drug
29 products unless the pharmacy has obtained a sterile compounding
30 pharmacy license from the board pursuant to this section. The
31 license shall be renewed annually and is not transferable.

32 (b) A license to compound sterile drug products shall be issued
33 only to a location that is licensed as a pharmacy and shall be issued
34 only to the owner of the pharmacy licensed at that location.

35 (c) A license to compound sterile drug products shall not be
36 issued or renewed until the location is inspected by the board and
37 found in compliance with this article and regulations adopted by
38 the board.

39 (d) A license to compound sterile drug products shall not be
40 issued or renewed until the board does all of the following:

1 (1) Reviews a current copy of the pharmacy's policies and
2 procedures for sterile compounding.

3 (2) Reviews the pharmacy's completed self-assessment form
4 required by Section 1735.2 of Title 16 of the California Code of
5 Regulations.

6 (3) Is provided with copies of all inspection reports conducted
7 of the pharmacy's premises, and any reports from a private
8 accrediting agency, conducted in the prior 12 months documenting
9 the pharmacy's operations.

10 (4) Receives a list of all sterile medications compounded by the
11 pharmacy since the last license renewal.

12 (e) A pharmacy licensed pursuant to this section shall do all of
13 the following:

14 (1) Provide to the board a copy of any disciplinary or other
15 action taken by another state within 10 days of the action.

16 (2) Notify the board within 10 days of the suspension of any
17 accreditation held by the pharmacy.

18 (3) Provide to the board, within 12 hours, any recall notice
19 issued by the pharmacy for sterile drug products it has
20 compounded.

21 (f) Adverse effects reported or potentially attributable to a
22 pharmacy's sterile drug product shall be immediately reported to
23 the board and the MedWatch program of the federal Food and
24 Drug Administration.

25 (g) The reconstitution of a sterile powder shall not require a
26 license pursuant to this section if both of the following
27 requirements are met:

28 (1) The sterile powder was obtained from a manufacturer.

29 (2) The drug is reconstituted for administration to patients by
30 a health care professional licensed to administer drugs by injection
31 pursuant to this division.

32 (h) This section shall become operative on July 1, 2014.

33 SEC. 6. Section 4127.2 of the Business and Professions Code
34 is amended to read:

35 4127.2. (a) A nonresident pharmacy shall not compound
36 injectable sterile drug products for shipment into the State of
37 California without a license issued by the board pursuant to this
38 section. The license shall be renewed annually and shall not be
39 transferable.

(b) A license to compound injectable sterile drug products may only be issued for a location that is licensed as a nonresident pharmacy. Furthermore, the license to compound injectable sterile drug products may only be issued to the owner of the nonresident pharmacy license at that location. A license to compound injectable sterile drug products may not be issued or renewed until the board receives the following from the nonresident pharmacy:

(1) A copy of an inspection report issued by the pharmacy's licensing agency, or a report from a private accrediting agency approved by the board, in the prior 12 months documenting the pharmacy's compliance with board regulations regarding the compounding of injectable sterile drug products.

(2) A copy of the nonresident pharmacy's proposed policies and procedures for sterile compounding.

(c) Nonresident pharmacies operated by entities that are licensed as a hospital, home health agency, or a skilled nursing facility and have current accreditation from the Joint Commission on Accreditation of Healthcare Organizations, or other private accreditation agencies approved by the board, are exempt from the requirement to obtain a license pursuant to this section.

(d) This section shall become inoperative on July 1, 2014, and, as of January 1, 2015, is repealed, unless a later enacted statute, that becomes operative on or before January 1, 2015, deletes or extends the dates on which it becomes inoperative and is repealed.

SEC. 7. Section 4127.2 is added to the Business and Professions Code, to read:

4127.2. (a) A nonresident pharmacy shall not compound sterile drug products for shipment into this state without a sterile compounding pharmacy license issued by the board pursuant to this section. The license shall be renewed annually and shall not be transferable.

(b) A license to compound sterile drug products shall be issued only to a location that is licensed as a nonresident pharmacy and shall be issued only to the owner of the nonresident pharmacy licensed at that location.

(c) A license to compound sterile drug products shall not be issued or renewed until the location is inspected by the board and found in compliance with this article and any regulations adopted by the board. The nonresident pharmacy shall reimburse the board for all actual and necessary costs incurred by the board in

1 conducting an inspection of the pharmacy at least once annually
2 pursuant to subdivision (v) of Section 4400.

3 (d) A license to compound sterile drug products shall not be
4 issued or renewed until the board does all of the following:

5 (1) Reviews a current copy of the nonresident pharmacy's
6 policies and procedures for sterile compounding.

7 (2) Reviews the pharmacy's completed self-assessment form
8 required by Section 1735.2 of Title 16 of the California Code of
9 Regulations.

10 (3) Is provided with copies of all inspection reports conducted
11 of the nonresident pharmacy's premises, and any reports from a
12 private accrediting agency, conducted in the prior 12 months
13 documenting the nonresident pharmacy's operations.

14 (4) Receives a list of all sterile drug products compounded by
15 the pharmacy within the prior 12 months.

16 (e) A pharmacy licensed pursuant to this section shall do all of
17 the following:

18 (1) Provide to the board a copy of any disciplinary or other
19 action taken by its state of residence or another state within 10
20 days of the action.

21 (2) Notify the board within 10 days of the suspension of any
22 accreditation held by the pharmacy.

23 (3) Provide to the board, within 12 hours, any recall notice
24 issued by the pharmacy for sterile drug products it has compounded
25 that have been shipped into, or dispensed in, California.

26 (4) Advise the board of any complaint it receives from a
27 provider, pharmacy, or patient in California.

28 (f) Adverse effects reported or potentially attributable to a
29 nonresident pharmacy's sterile compounded drug product shall be
30 immediately reported to the board and the MedWatch program of
31 the federal Food and Drug Administration.

32 (g) This section shall become operative on July 1, 2014.

33 SEC. 8. Section 4400 of the Business and Professions Code is
34 amended to read:

35 4400. The amount of fees and penalties prescribed by this
36 chapter, except as otherwise provided, is that fixed by the board
37 according to the following schedule:

38 (a) The fee for a nongovernmental pharmacy license shall be
39 four hundred dollars (\$400) and may be increased to five hundred
40 twenty dollars (\$520). The fee for the issuance of a temporary

1 nongovernmental pharmacy permit shall be two hundred fifty
2 dollars (\$250) and may be increased to three hundred twenty-five
3 dollars (\$325).

4 (b) The fee for a nongovernmental pharmacy license annual
5 renewal shall be two hundred fifty dollars (\$250) and may be
6 increased to three hundred twenty-five dollars (\$325).

7 (c) The fee for the pharmacist application and examination shall
8 be two hundred dollars (\$200) and may be increased to two
9 hundred sixty dollars (\$260).

10 (d) The fee for regrading an examination shall be ninety dollars
11 (\$90) and may be increased to one hundred fifteen dollars (\$115).
12 If an error in grading is found and the applicant passes the
13 examination, the regrading fee shall be refunded.

14 (e) The fee for a pharmacist license and biennial renewal shall
15 be one hundred fifty dollars (\$150) and may be increased to one
16 hundred ninety-five dollars (\$195).

17 (f) The fee for a nongovernmental wholesaler license and annual
18 renewal shall be six hundred dollars (\$600), and may be increased
19 to seven hundred eighty dollars (\$780). The application fee for
20 any additional location after licensure of the first 20 locations shall
21 be two hundred twenty-five dollars (\$225) and may be increased
22 to three hundred dollars (\$300). A temporary license fee shall be
23 five hundred fifty dollars (\$550) and may be increased to seven
24 hundred fifteen dollars (\$715).

25 (g) The fee for a hypodermic license and renewal shall be one
26 hundred twenty-five dollars (\$125) and may be increased to one
27 hundred sixty-five dollars (\$165).

28 (h) (1) The fee for application, investigation, and issuance of
29 license as a designated representative pursuant to Section 4053
30 shall be two hundred fifty-five dollars (\$255) and may be increased
31 to three hundred thirty dollars (\$330).

32 (2) The fee for the annual renewal of a license as a designated
33 representative shall be one hundred fifty dollars (\$150) and may
34 be increased to one hundred ninety-five dollars (\$195).

35 (i) (1) The fee for the application, investigation, and issuance
36 of a license as a designated representative for a veterinary
37 food-animal drug retailer pursuant to Section 4053 shall be two
38 hundred fifty-five dollars (\$255) and may be increased to three
39 hundred thirty dollars (\$330).

1 (2) The fee for the annual renewal of a license as a designated
2 representative for a veterinary food-animal drug retailer shall be
3 one hundred fifty dollars (\$150) and may be increased to one
4 hundred ninety-five dollars (\$195).

5 (j) (1) The application fee for a nonresident wholesaler's license
6 issued pursuant to Section 4161 shall be six hundred dollars (\$600)
7 and may be increased to seven hundred eighty dollars (\$780).

8 (2) For nonresident wholesalers who have 21 or more facilities
9 operating nationwide the application fees for the first 20 locations
10 shall be six hundred dollars (\$600) and may be increased to seven
11 hundred eighty dollars (\$780). The application fee for any
12 additional location after licensure of the first 20 locations shall be
13 two hundred twenty-five dollars (\$225) and may be increased to
14 three hundred dollars (\$300). A temporary license fee shall be five
15 hundred fifty dollars (\$550) and may be increased to seven hundred
16 fifteen dollars (\$715).

17 (3) The annual renewal fee for a nonresident wholesaler's license
18 issued pursuant to Section 4161 shall be six hundred dollars (\$600)
19 and may be increased to seven hundred eighty dollars (\$780).

20 (k) The fee for evaluation of continuing education courses for
21 accreditation shall be set by the board at an amount not to exceed
22 forty dollars (\$40) per course hour.

23 (l) The fee for an intern pharmacist license shall be ninety dollars
24 (\$90) and may be increased to one hundred fifteen dollars (\$115).
25 The fee for transfer of intern hours or verification of licensure to
26 another state shall be twenty-five dollars (\$25) and may be
27 increased to thirty dollars (\$30).

28 (m) The board may waive or refund the additional fee for the
29 issuance of a license where the license is issued less than 45 days
30 before the next regular renewal date.

31 (n) The fee for the reissuance of any license, or renewal thereof,
32 that has been lost or destroyed or reissued due to a name change
33 shall be thirty-five dollars (\$35) and may be increased to forty-five
34 dollars (\$45).

35 (o) The fee for the reissuance of any license, or renewal thereof,
36 that must be reissued because of a change in the information, shall
37 be one hundred dollars (\$100) and may be increased to one hundred
38 thirty dollars (\$130).

39 (p) It is the intent of the Legislature that, in setting fees pursuant
40 to this section, the board shall seek to maintain a reserve in the

1 Pharmacy Board Contingent Fund equal to approximately one
2 year's operating expenditures.

3 (q) The fee for any applicant for a nongovernmental clinic
4 license shall be four hundred dollars (\$400) and may be increased
5 to five hundred twenty dollars (\$520) for each license. The annual
6 fee for renewal of the license shall be two hundred fifty dollars
7 (\$250) and may be increased to three hundred twenty-five dollars
8 (\$325) for each license.

9 (r) The fee for the issuance of a pharmacy technician license
10 shall be eighty dollars (\$80) and may be increased to one hundred
11 five dollars (\$105). The fee for renewal of a pharmacy technician
12 license shall be one hundred dollars (\$100) and may be increased
13 to one hundred thirty dollars (\$130).

14 (s) The fee for a veterinary food-animal drug retailer license
15 shall be four hundred five dollars (\$405) and may be increased to
16 four hundred twenty-five dollars (\$425). The annual renewal fee
17 for a veterinary food-animal drug retailer license shall be two
18 hundred fifty dollars (\$250) and may be increased to three hundred
19 twenty-five dollars (\$325).

20 (t) The fee for issuance of a retired license pursuant to Section
21 4200.5 shall be thirty-five dollars (\$35) and may be increased to
22 forty-five dollars (\$45).

23 (u) The fee for issuance or renewal of a nongovernmental license
24 to compound sterile drug products shall be six hundred dollars
25 (\$600) and may be increased to seven hundred eighty dollars
26 (\$780). The fee for a temporary license shall be five hundred fifty
27 dollars (\$550) and may be increased to seven hundred fifteen
28 dollars (\$715).

29 (v) This section shall become inoperative on July 1, 2014, and,
30 as of January 1, 2015, is repealed, unless a later enacted statute,
31 that becomes operative on or before January 1, 2015, deletes or
32 extends the dates on which it becomes inoperative and is repealed.

33 SEC. 9. Section 4400 is added to the Business and Professions
34 Code, to read:

35 4400. The amount of fees and penalties prescribed by this
36 chapter, except as otherwise provided, is that fixed by the board
37 according to the following schedule:

38 (a) The fee for a nongovernmental pharmacy license shall be
39 four hundred dollars (\$400) and may be increased to five hundred
40 twenty dollars (\$520). The fee for the issuance of a temporary

1 nongovernmental pharmacy permit shall be two hundred fifty
2 dollars (\$250) and may be increased to three hundred twenty-five
3 dollars (\$325).

4 (b) The fee for a nongovernmental pharmacy license annual
5 renewal shall be two hundred fifty dollars (\$250) and may be
6 increased to three hundred twenty-five dollars (\$325).

7 (c) The fee for the pharmacist application and examination shall
8 be two hundred dollars (\$200) and may be increased to two
9 hundred sixty dollars (\$260).

10 (d) The fee for regrading an examination shall be ninety dollars
11 (\$90) and may be increased to one hundred fifteen dollars (\$115).
12 If an error in grading is found and the applicant passes the
13 examination, the regrading fee shall be refunded.

14 (e) The fee for a pharmacist license and biennial renewal shall
15 be one hundred fifty dollars (\$150) and may be increased to one
16 hundred ninety-five dollars (\$195).

17 (f) The fee for a nongovernmental wholesaler license and annual
18 renewal shall be six hundred dollars (\$600), and may be increased
19 to seven hundred eighty dollars (\$780). The application fee for
20 any additional location after licensure of the first 20 locations shall
21 be two hundred twenty-five dollars (\$225) and may be increased
22 to three hundred dollars (\$300). A temporary license fee shall be
23 five hundred fifty dollars (\$550) and may be increased to seven
24 hundred fifteen dollars (\$715).

25 (g) The fee for a hypodermic license and renewal shall be one
26 hundred twenty-five dollars (\$125) and may be increased to one
27 hundred sixty-five dollars (\$165).

28 (h) (1) The fee for application, investigation, and issuance of
29 license as a designated representative pursuant to Section 4053
30 shall be two hundred fifty-five dollars (\$255) and may be increased
31 to three hundred thirty dollars (\$330).

32 (2) The fee for the annual renewal of a license as a designated
33 representative shall be one hundred fifty dollars (\$150) and may
34 be increased to one hundred ninety-five dollars (\$195).

35 (i) (1) The fee for the application, investigation, and issuance
36 of a license as a designated representative for a veterinary
37 food-animal drug retailer pursuant to Section 4053 shall be two
38 hundred fifty-five dollars (\$255) and may be increased to three
39 hundred thirty dollars (\$330).

(2) The fee for the annual renewal of a license as a designated representative for a veterinary food-animal drug retailer shall be one hundred fifty dollars (\$150) and may be increased to one hundred ninety-five dollars (\$195).

(j) (1) The application fee for a nonresident wholesaler's license issued pursuant to Section 4161 shall be six hundred dollars (\$600) and may be increased to seven hundred eighty dollars (\$780).

(2) For nonresident wholesalers who have 21 or more facilities operating nationwide the application fees for the first 20 locations shall be six hundred dollars (\$600) and may be increased to seven hundred eighty dollars (\$780). The application fee for any additional location after licensure of the first 20 locations shall be two hundred twenty-five dollars (\$225) and may be increased to three hundred dollars (\$300). A temporary license fee shall be five hundred fifty dollars (\$550) and may be increased to seven hundred fifteen dollars (\$715).

(3) The annual renewal fee for a nonresident wholesaler's license issued pursuant to Section 4161 shall be six hundred dollars (\$600) and may be increased to seven hundred eighty dollars (\$780).

(k) The fee for evaluation of continuing education courses for accreditation shall be set by the board at an amount not to exceed forty dollars (\$40) per course hour.

(l) The fee for an intern pharmacist license shall be ninety dollars (\$90) and may be increased to one hundred fifteen dollars (\$115). The fee for transfer of intern hours or verification of licensure to another state shall be twenty-five dollars (\$25) and may be increased to thirty dollars (\$30).

(m) The board may waive or refund the additional fee for the issuance of a license where the license is issued less than 45 days before the next regular renewal date.

(n) The fee for the reissuance of any license, or renewal thereof, that has been lost or destroyed or reissued due to a name change shall be thirty-five dollars (\$35) and may be increased to forty-five dollars (\$45).

(o) The fee for the reissuance of any license, or renewal thereof, that must be reissued because of a change in the information, shall be one hundred dollars (\$100) and may be increased to one hundred thirty dollars (\$130).

(p) It is the intent of the Legislature that, in setting fees pursuant to this section, the board shall seek to maintain a reserve in the

1 Pharmacy Board Contingent Fund equal to approximately one
2 year's operating expenditures.

3 (q) The fee for any applicant for a nongovernmental clinic
4 license shall be four hundred dollars (\$400) and may be increased
5 to five hundred twenty dollars (\$520) for each license. The annual
6 fee for renewal of the license shall be two hundred fifty dollars
7 (\$250) and may be increased to three hundred twenty-five dollars
8 (\$325) for each license.

9 (r) The fee for the issuance of a pharmacy technician license
10 shall be eighty dollars (\$80) and may be increased to one hundred
11 five dollars (\$105). The fee for renewal of a pharmacy technician
12 license shall be one hundred dollars (\$100) and may be increased
13 to one hundred thirty dollars (\$130).

14 (s) The fee for a veterinary food-animal drug retailer license
15 shall be four hundred five dollars (\$405) and may be increased to
16 four hundred twenty-five dollars (\$425). The annual renewal fee
17 for a veterinary food-animal drug retailer license shall be two
18 hundred fifty dollars (\$250) and may be increased to three hundred
19 twenty-five dollars (\$325).

20 (t) The fee for issuance of a retired license pursuant to Section
21 4200.5 shall be thirty-five dollars (\$35) and may be increased to
22 forty-five dollars (\$45).

23 (u) The fee for issuance or renewal of a nongovernmental sterile
24 compounding pharmacy license shall be six hundred dollars (\$600)
25 and may be increased to seven hundred eighty dollars (\$780). The
26 fee for a temporary license shall be five hundred fifty dollars (\$550)
27 and may be increased to seven hundred fifteen dollars (\$715).

28 (v) The fee for the issuance or renewal of a nonresident sterile
29 compounding pharmacy license shall be seven hundred eighty
30 dollars (\$780). In addition to paying that application fee, the
31 nonresident sterile compounding pharmacy shall deposit, when
32 submitting the application, a reasonable amount, as determined by
33 the board, necessary to cover the board's estimated cost of
34 performing the inspection required by Section 4127.2. If the
35 required deposit is not submitted with the application, the
36 application shall be deemed to be incomplete. If the actual cost of
37 the inspection exceeds the amount deposited, the board shall
38 provide to the applicant a written invoice for the remaining amount
39 and shall not take action on the application until the full amount
40 has been paid to the board. If the amount deposited exceeds the

1 amount of actual and necessary costs incurred, the board shall
2 remit the difference to the applicant.

3 (w) This section shall become operative on July 1, 2014.

4 SEC. 10. No reimbursement is required by this act pursuant to
5 Section 6 of Article XIII B of the California Constitution because
6 the only costs that may be incurred by a local agency or school
7 district will be incurred because this act creates a new crime or
8 infraction, eliminates a crime or infraction, or changes the penalty
9 for a crime or infraction, within the meaning of Section 17556 of
10 the Government Code, or changes the definition of a crime within
11 the meaning of Section 6 of Article XIII B of the California
12 Constitution.